UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/434,382	11/05/99	TAVTIGIAN S	2318-247

HM12/0110

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EXAMINER	
HUNT, J	
ART UNIT	**PAPER NUMBER**
1642	5

DATE MAILED: 01/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/434,382	Tavtigian et al.
Examiner	**Group Art Unit**
Jennifer Nichols, Nee Hunt	1642

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-60* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-60* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, and 25-26 drawn to nucleic acids and primers, and corresponding vectors, host cells, method of making a polypeptide, classified in class 536, subclass 23.1, class 435, subclass 320.1 and 325.

II. Claims 16-19 and 21-22, drawn to polypeptides, fragments thereof, and corresponding fusion proteins, classified in class 530, subclass 350.

III. Claim 20, drawn to an antibody which binds the polypeptide of claim 16, classified in class 530, subclass 387.1.

IV. Claims 23-24, drawn to a method of making the antibody of claim 20, classified in class 530, subclass 387.1.

V. Claims 27-31, drawn to a method of detecting a mutation or alteration in HPC2, classified in class 436, subclass 501.

VI. Claims 32-36, drawn to a transgenic animal and corresponding cells therefrom, classified in class 800, subclass 2.

VII. Claim 37, drawn to a mutant HPC2, classified in class 530, subclass 350.

VIII. Claims 38-39, drawn to an HPC2 complex, classified in class 530, subclass 402.

IX. Claims 40-42, drawn to an antibody which binds the complex of claims 38-39, classified in class 530, subclass 387.1.

X. Claims 43-45, drawn to gene therapy, classified in class 514, subclass 44.

XI. Claims 46-52, drawn to assay for the ability to form a complex, classified in class 436, subclass 501.

XII. Claims 53-56, drawn to a method of drug screening by measuring polypeptide activity, classified in class 530, subclass 350.

XIII. Claims 57-59, drawn to a method of drug screening using transgenic animals, classified in class 800, subclass 2.

XIV. Claim 60, drawn to a method of drug screening using an in vitro cell culture, classified in class 435, subclass 325.

2. The inventions are distinct, each from the other because of the following reasons:

The products of Groups I-III and VI-IX are completely different products, having different biological structures, activities, and properties. The product of Group I consists of nucleic acids and primers, and corresponding vectors, host cells, and methods of making polypeptides. The product of Group II consists of polypeptides, fragments and fusion proteins. The product of Group III consists of an antibody. These are all distinct biological structures, having different chemical make-ups, and biological properties and functions. The product of Group VI is drawn to a transgenic animal, which is distinct and different in structure, function, and properties from the aforementioned nucleic acids, polypeptides and antibodies. The product of Group VII consists of a mutant polypeptide, having a different structure and function from the polypeptide of Group II, as well as the other groups of nucleic acids, antibodies, and transgenic

animals. Group VIII is drawn to a complex, and thus has a multitude of compounds, who's structure and ultimate function clearly differ from the previously recited nucleic acids, polypeptides, antibodies, transgenic animals, and mutant polypeptides. Lastly, Group IX is drawn to an antibody which binds to the complex of Group VIII and thus has different structure and function than the antibody of Group III and further from the products of the other aforementioned groups. Thus, as set forth above, the products of Groups I-III and VI-IX are completely different products, which have different biological structures, functions and physiological roles.

The methods of Groups IV-V and X-XIV are completely different methods, having different starting points and reactants, different method steps, and distinct ultimate outcomes. The method of Group IV begins with a polypeptide and ultimately produces an antibody. The method of Group V begins with nucleotide sequences and uses them to determine a mutant. The method of Group X begins with a cell, introduces a nucleic acid to supply a previously absent function. Group XI begins with a fragment and determines it's ability to form a complex as a measure of an individual's predisposition to cancer. Group XII begins with a mutant and a wild-type polypeptide and a drug compound and uses them to determine the drug's effect on binding. Group XIII begins with a transgenic animal and a drug compound and uses the animal to determine if the drug is effect in vivo. Group XIV begins with a mutant cell culture and a wild-type cell culture and a drug compound and uses them to determine the drug's effect on cancer. Therefor, as set forth above, the methods of Groups IV-V and X-XIV are completely different

methods, having different starting points and reactants, different method steps, and distinct ultimate outcomes.

3. Inventions of Groups III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Group III can be made by a materially different process, such as by isolation and purification.

4. Inventions of Groups I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the primers of Group I can also be used for PCR.

5. Inventions of Groups VI and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group VI can be used to study disease progress.

6. Inventions of Groups I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used to produce recombinant polypeptides.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for any one Group is not required for any other Group , restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Nichols, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**anthony.caputa@uspto.gov**].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Nichols, Nee Hunt

January 5, 2001

Brenda Brumback
BRENDA BRUMBACK
PATENT EXAMINER